

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	Criminal Action
v.	)	No. 09-10330-GAO
	)	
STRYKER BIOTECH, LLC,	)	
et al.,	)	
	)	
Defendants.	)	
	)	

BEFORE THE HONORABLE GEORGE A. O'TOOLE, JR.  
UNITED STATES DISTRICT JUDGE

**DAY FIVE  
JURY TRIAL**

**EXCERPT - OPENING STATEMENTS**

John J. Moakley United States Courthouse  
Courtroom No. 9  
One Courthouse Way  
Boston, Massachusetts 02210  
Friday, January 13, 2012  
9:07 a.m.

Marcia G. Patrisso, RMR, CRR  
Official Court Reporter  
John J. Moakley U.S. Courthouse  
One Courthouse Way, Room 3510  
Boston, Massachusetts 02210  
(617) 737-8728

Mechanical Steno - Computer-Aided Transcript

## 1 APPEARANCES:

2 OFFICE OF THE UNITED STATES ATTORNEY  
By: Jeremy M. Sternberg, Susan B. Winkler, and  
3 Gregory F. Noonan, Assistant U.S. Attorneys  
John Joseph Moakley Federal Courthouse  
4 Suite 9200  
Boston, Massachusetts 02210  
5 On Behalf of the Government

6 ROPES & GRAY  
By: Brien T. O'Connor, Esq.  
7 Joshua S. Levy, Esq.  
Aaron M. Katz, Esq.  
8 Cori A. Lable, Esq.  
Prudential Tower  
9 800 Boylston Street  
Boston, Massachusetts 02199-3600  
10 On Behalf of the Defendant Stryker Biotech, LLC

11 NUTTER, MCCLENNEN & FISH, LLP  
By: Robert L. Ullmann, Esq.  
12 Maya L. Sethi, Esq.  
Seaport West  
13 155 Seaport Boulevard  
Boston, Massachusetts 02210-2604  
14 On Behalf of the Defendant William Heppner

15 WILMER CUTLER PICKERING HALE & DORR, LLP  
By: Brent J. Gurney, Esq.  
16 Miranda Hooker, Esq.  
1875 Pennsylvania Avenue  
17 Washington, D.C. 20006  
On Behalf of the Defendant David Ard

18 LIBBY HOOPEES, P.C.  
By: Frank A. Libby, Jr.  
19 Alatheia E. Porter, Esq.  
20 175 Federal Street  
Boston, Massachusetts 02110  
21 On Behalf of the Defendant Jeffrey Whitaker

22  
23  
24  
25

1 MR. LIBBY: May it please the Court, counsel, and may  
2 it please you, ladies and gentlemen of the jury. Once again,  
3 my name's Frank Libby, and together with my colleague, Althea  
4 Porter, we're proud to represent Jeff Whitaker.

5 You've been very patient yesterday and again this  
6 morning. You've heard a great deal already. A lot of  
7 material. Several hours of presentation by some very  
8 experienced counsel on a matter that's very likely unfamiliar  
9 to you. And I was planning on asking you to hang in there just  
10 a little bit longer, telling you that it was just one more  
11 opening statement, but that wouldn't do justice to this moment  
12 because it doesn't come near capturing what's really unfolding  
13 before you right now.

14 I'm standing before you on behalf of a good and decent  
15 man. His entire life he cared deeply about how he carries  
16 himself, how he behaves, how others view him. He cares deeply  
17 about his family, his friends, his colleagues at Stryker and in  
18 the relatively small surgical community, surgeons and the like,  
19 what they think about, what they say about him. Simply put:  
20 Jeff Whitaker is eager to be both exonerated in this criminal  
21 matter and to clear his good name, the name that he has built  
22 up his entire life.

23 He wants to do that very much in the course of this  
24 proceeding with you, and he wants to get this  
25 process -- everybody wants to get this process underway, with

1 you all as the judges of the facts. You and you alone find the  
2 facts in this case. And that begins with testimony which  
3 commences virtually immediately after I'm done. But I make no  
4 apology for taking this time with you.

5 So Jeff Whitaker: He's a family man. Married Linda  
6 about 20 years ago. Two young children: Jacob and Hannah.  
7 She's home taking care of them. Jeff grew up and attended high  
8 school in Maryland and South Carolina, and graduated college in  
9 1985. He bounced around at a couple of entry-level positions  
10 after graduating college and then had the great fortune to join  
11 the medical-device industry.

12 His first job in the medical-device field had to do  
13 with legs, anti-coagulation devices and the like. Prevents  
14 deep vein thrombosis. So why is that important to mention?  
15 Because it was his first opportunity to deal with a very select  
16 customer base: doctors, surgeons. He called on them. He  
17 found it was an exciting new world. These are busy people with  
18 serious work. And he came to appreciate what they're able to  
19 do and how they go about their work.

20 He came to know and respect individual surgeons not in  
21 the role of a patient like you or I would typically, but to  
22 present himself as a potential asset, a resource to that  
23 surgeon, to that doctor. And after some time Jeff concluded,  
24 Do you know what? This is pretty good. This is a great way to  
25 make a living. This is meaningful and this is what I want to

1 do.

2 So after some time he moved on from legs to knees. He  
3 worked for a company that sold surgical instruments for  
4 arthroscopic surgery and the like, provided stability to the  
5 knees. And then moved up to the shoulders. Started with legs,  
6 knees, now shoulders, rotator-cuff surgery-type instruments,  
7 and so on, suture anchors, to stabilize the shoulder.

8 In 2002 Jeff had the great fortune to join Stryker  
9 Biotech. And what an opportunity. He moves from  
10 instrumentation-type devices to the cutting-edge world of  
11 biologics. His initial experience was with OP-1 Implant.  
12 Mr. O'Connor told you a little bit of history about OP-1  
13 Implant with the long-bone nonunion product. A year or so  
14 later Implant was joined on the market by OP-1 Putty. You  
15 heard a great deal about that already. That's the bone  
16 morphogenetic protein.

17 Now, here some of the most demanding customers on the  
18 planet, neurosurgeons, orthopedic surgeons, he's dealing with  
19 them on a routine basis. It's a demanding task, but if you  
20 know your stuff and you're good at what you do and you know  
21 people -- and sales is all about people. It's all about trust  
22 and confidence -- you can build solid working and professional  
23 relationships and you have a shot at growing a loyal customer  
24 base, customers who will not only come to know you and respect  
25 you and trust you, but give your name to other surgeons.

1 That's how you make a good living and you carve out a career  
2 for yourself, a future for yourself and your family.

3 Now, you heard from Ms. Winkler, Jeff was a regional  
4 sales manager for Stryker. He was proud to be a regional sales  
5 manager for Stryker. In '05 he became the southeast sales  
6 manager, and then in late '07 he became the eastern region  
7 sales manager. Now, it's not a manager in the executive sense  
8 of the word. He worked out of his home, North Carolina. He  
9 doesn't hire or fire. He doesn't make salary decisions or  
10 design training in any way. That's all handled elsewhere in  
11 the company. But he's an experienced sales motivator, a  
12 communicator and a facilitator for the ten or so reps that he  
13 covers in his territory.

14 And that includes traveling throughout his region,  
15 supporting his reps, looking after their well-being, and going  
16 on things you'll hear called ride-alongs. A territory  
17 manager -- or, rather, a sales manager, a regional manager,  
18 will go and see a rep and go on some rides, pay visits to  
19 surgeons in their offices, see how his reps are handling  
20 themselves in the field.

21 So from years of experience in the surgeons' offices,  
22 in and around hospitals and surgical clinics, Jeff helped his  
23 sales reps learn the ropes, learn -- he learned the ropes, and  
24 he would teach his reps how best to prepare to help the surgeon  
25 and actually be helpful to that surgeon. You'll see and learn

1     how his own people uniformly thought very highly of him; valued  
2     his energy, his willingness to step up and to help with  
3     whatever they needed.

4             So let's fast-forward to the present. Jeff's day in  
5     court begins right now -- right here, right now. And this is  
6     my opportunity on behalf of Jeff to tell you what I believe  
7     this case is fundamentally all about. Now, I'm not going to  
8     intentionally go into plowing the ground that these lawyers did  
9     yesterday. I'm not going to try to do that. I'm going to try  
10    to avoid that. There may be some overlap, but I'll see if I  
11    can avoid it. Rather, I'm going to suggest to you two, and  
12    only two, guideposts to keep in mind as you listen to the  
13    testimony, you see the evidence, you hear the people from the  
14    witness stand.

15            And those two points -- each of those two points have  
16    to do with one thing, and that's being free to do your job.  
17    Being free to do your job. One -- Mr. O'Connor briefly  
18    mentioned this yesterday and I want to underscore it -- the FDA  
19    may not interfere in the practice of medicine. The FDA may not  
20    interfere in the practice of medicine. That means doctors,  
21    surgeons, are free to call the shots -- all of them, because  
22    it's their obligation to call the shots -- regarding the care  
23    and treatment of their respective patients.

24            The FDA's role as a regulator is, of course,  
25    important, but at the end of the day -- at the end of the

1 day -- it's the surgeon's decision. And the surgeon's decision  
2 regarding his patient trumps the FDA, something you didn't hear  
3 from Ms. Winkler yesterday. That's one.

4 Two: When a surgeon asks for help or poses a question  
5 to a manufacturer's rep, a sales rep, regarding the care or  
6 treatment of that surgeon's patient, the rep -- such as Jeff is  
7 a rep, now he's a regional manager -- they're completely free  
8 to respond -- completely free to respond -- to that request for  
9 help, or that question. Another item not included in  
10 Ms. Winkler's comments.

11 Now, doctors know this. They know they're free to  
12 practice medicine, and so do those in the medical-device  
13 community, including Jeff. He knows it too. You'll see from  
14 the evidence that Jeff acted in good faith, that whatever the  
15 circumstances were, he believed he should be prepared to  
16 respond and that it was perfectly permissible to respond to  
17 that request for help.

18 Now, why do I single out these two points up-front  
19 first? Because the government has charged Jeffrey Whitaker  
20 with fraud; that is, lying and cheating surgeons. Lying and  
21 cheating surgeons. Make no mistake. That's the  
22 charges -- those are the charges in this case. And to convict,  
23 they have to prove to you, ladies and gentlemen, among other  
24 things, and beyond a reasonable doubt, that Jeff -- this man,  
25 Jeffrey Whitaker, had criminal intent. And not just any kind



1 of intent -- any kind of criminal intent -- specific intent.  
2 Specifically intended to defraud a surgeon, to lie, to cheat a  
3 surgeon. And here's the home-run point: Good faith is  
4 completely inconsistent with an intent to defraud. Completely  
5 inconsistent with an intent to defraud.

6 You will conclude that after all is said and done and  
7 all the evidence is in in this case, contrary to believing that  
8 any of his actions were criminal, Jeff had every good reason to  
9 believe and, in fact, believed genuinely that he was acting in  
10 good faith. He was doing good. Helping a surgeon, in turn,  
11 help that surgeon's patient.

12 So here let me be a little more visual and offer a  
13 scenario where both of those things are in play.

14 If I may, your Honor?

15 THE COURT: Go ahead.

16 MR. LIBBY: It's going to be to your back, but this is  
17 what we have here. Can everybody see this okay?

18 Now, these two principles I'm talking about are  
19 actually at play in what you see here in this photograph. And  
20 they're at play with -- everybody in this room has to be on his  
21 or her own toes. And that takes place every day in every  
22 operating room in this nation.

23 One way or another, virtually everything you hear and  
24 see in this case is going to come down to this. All of it.  
25 All the evidence in this case. Everything you need to decide

1 about the government's charges can be found right here. It's  
2 personified in what you see here.

3 This is the operating suite, the operating room.  
4 You're going to learn from the evidence in this case, ladies  
5 and gentlemen, how the surgeon, this gentleman right here with  
6 his back to you, bent over as tasked, calls all the shots in  
7 the operating room to include who's in the room, what takes  
8 place, at what stage, in what manner, and for what purpose.  
9 Everything. The surgeon.

10 So it's a little tight quarters here and it doesn't  
11 capture everybody in the room, but just so we're clear we have  
12 a patient you can't see. The surgeon is bent over him. We've  
13 got the scrub nurse, the surgical assistant; we've got the  
14 neurology, radiology folks. Why do we have radiology? We're  
15 dealing with spines, bones, constantly taking X-rays. That's  
16 why we're wearing lead vests.

17 We have a circulating nurse -- not in the photograph  
18 here, but every one of these procedures -- you'll learn about  
19 the surgical procedure, including who's in a room, what  
20 happens. A circulating nurse is not in the sterile field.  
21 That's the area immediately above the incision. Nothing can go  
22 in there unless it's sterile. It's called the sterile field.  
23 The circulating nurse gets whatever product, boxes, opens the  
24 boxes, makes sure the instruments from the back table are made  
25 available to the scrub nurse and so forth. So it goes

1 circulating nurse to scrub nurse to the assistant, and  
2 ultimately, the surgeon.

3 And that circulating nurse is documenting in real time  
4 everything that is being used in that surgery. Everything.  
5 Documenting it so there's a record, a real-time record so  
6 you'll know -- and you can see. And you'll see documents in  
7 this case -- what happened in that room, two- or three-hour  
8 procedure. A complete record. What was used, who was there,  
9 who did what, when.

10 Now, I haven't talked about this fellow right here in  
11 the red vest. This might surprise you, but that's the  
12 medical-device representative. Why's he there? Well, we'll  
13 tell you later. You'll learn why he's there. He's there often  
14 at the request, and most often at the insistence, of this man,  
15 the surgeon. He's not barging in. He's expected to be there  
16 under the complete direction and control of the surgeon.

17 Now, here he's using a laser pen. You'll see here,  
18 you'll learn that because the rep is not in the sterile field  
19 and he's not scrubbed in and he's not, in fact, involved in any  
20 way physically with the surgery, he needs to point out  
21 products, boxes and so forth, and talk to the circulating nurse  
22 and make sure that people are getting what needs to be gotten.

23 He never opens a box or moves or touches an  
24 instrument, but -- and you'll hear about this too -- he can be  
25 helpful in telling the surgical team, maybe unfamiliar with the

1 vials -- and you've seen a couple of the vials of OP-1 and  
2 Calstrux in this case -- how to open it. It's not easy. It's  
3 got serrated edges; it's got rubber stoppers. They want to  
4 make sure that people open this properly when it's time. And  
5 this gentleman here says when it's time.

6 Now, he doesn't simply show up. These are calendared.  
7 These procedures -- as you might imagine, it's a fairly  
8 complex, significant procedure for everybody involved. There's  
9 a game plan. It's scheduled. Need to know who's on the team,  
10 who's going to be there, how much product is necessary. It's  
11 all played out ahead of time. It's too late once this  
12 procedure gets underway to try to figure out how much product  
13 is necessary for whatever the procedure is. So the bottom-line  
14 dynamic, you'll find -- you'll find in the course of this  
15 trial -- is that this person's purpose is to do all he or she  
16 can to help this person do all he or she can to help the  
17 patient. That's it. That's what this case is all about.

18 Now, the patient -- a word about the patient you don't  
19 see here in this photo. At this stage in this kind of  
20 surgery -- leading up to the surgery, rather, there's just only  
21 one word for this patient's life, and that's miserable.  
22 Whoever that person is has been dealing with spinal instability  
23 for years. After years of pain management and physical therapy  
24 and so forth and so on, this person has been effectively  
25 deprived of all daily functions of life and enjoyment of life.

1 They consider themselves out of the mainstream of family life  
2 and business life. They can't move. They can't bend over.  
3 They can't lift. They can't sleep. They can't walk. They're  
4 at the end of their rope.

5 Now, 20 years or so ago all that was available to help  
6 folks like that -- some folks like that -- was the procedure  
7 that Mr. O'Connor laid out for you yesterday, and that's the  
8 iliac crest graft surgery. Brutally painful. Even with  
9 anesthesia, brutally painful. Patients will tell you they  
10 don't want to go through that. They could feel the hollow  
11 piece from their hip. It's where they go in, they crack open  
12 the hip with a hammer and chisel and pull out that soft bone.  
13 They need the person's own bone to try to make a fusion in the  
14 spine, basically.

15 But for some they can't even -- years ago they  
16 couldn't even submit to that procedure. They were just flat  
17 out of luck. They weren't good candidates for it. And, again,  
18 Mr. O'Connor mentioned briefly some of those folks weren't good  
19 candidates because they didn't -- they had poor bone quality,  
20 if they had any bone available at all for that type of  
21 procedure, iliac crest graft. These are people who were  
22 elderly, smokers, diabetic, osteoporosis, had a prior failed  
23 surgery. There wasn't any bone left to go back and get. So  
24 their misery continued, no options.

25 Then along came bone morphogenic protein, a brand-new

1 day for spine surgery. A brand-new day for spine surgeons.  
2 And that's why, ladies and gentlemen, this man joined Stryker.  
3 He saw it for what it was: a great development. Patients were  
4 no longer shut out of the operating room by poor bone. It's a  
5 huge leap forward.

6 You heard Mr. O'Connor talk about Stryker's research  
7 and development story. This is the kind of -- this is the kind  
8 of product, this OP-1 -- it's like a radio signal. Very strong  
9 radio signal. A hundred, even a thousand times stronger than  
10 your own bone. Tells the body: Grow bone. Fill in, give me  
11 stability in my spine. Surgeons don't have to go and tell  
12 their patient, You've got to undergo this crest graft, this  
13 hip -- we're going to crack open your hip. He doesn't have to  
14 say that anymore. So most of all, with the advent of BMPs,  
15 surgeons can say yes to these people that were previously out  
16 of luck.

17 So in the course of this trial you're going to learn  
18 surgeons obviously wanted to avoid exposing their patients to  
19 this unnecessary pain, and not for nothing, additional surgical  
20 procedure concerning the risk of anesthesia and so on and so  
21 forth. Two procedures. They understood the benefit of BMPs.

22 A little bit of relevant history. Just a little. The  
23 first on the market was not OP-1. It was a thing called  
24 InFuse -- a product called InFuse -- from Medtronic. First on  
25 the market. The surgeons became familiar with InFuse, and then

1 they began combining InFuse with other materials to give it  
2 volume and handling, okay?

3 And the scaffolding. The scaffolding -- you heard the  
4 term "scaffolding" already. It's something to grow on. When  
5 the active ingredient sends that signal to grow bone, it's got  
6 to grow on something, to provide scaffolding. So doctors were  
7 already mixing before OP-1 came on the market. And all that  
8 was widely known in the spine surgery community and the  
9 medical-device community, known to Jeff. OP-1 later came on  
10 the market as an approved product. Now that's available to  
11 surgeons as well. And sometime later Stryker launched  
12 Calstrux, the TCP product, that tricalcium phosphate which  
13 occurs in things such as you see in this Gerber baby food.

14 You'll also hear a constant reframe, and the evidence  
15 in this case, and that is this: Surgeons ask each other and  
16 reps all the time about mixing, combining products. All the  
17 time. Mixing was the standard of care throughout this whole  
18 time. Surgeons believe that combining an active ingredient and  
19 inert materials such as TCP was beneficial. It was the best of  
20 both worlds. It provided the bone growth signal and the  
21 scaffolding on which to grow the bone. You're going to learn  
22 again that all of that was widely known in the medical-device  
23 community, to folks including Jeff.

24 Surgeons, their surgical teams and the sales reps  
25 providing the latest, greatest advancement all believed -- all

1 of them believed -- they were playing a genuine role towards  
2 greater prospects for successful surgical procedures. And  
3 you'll see and hear in this case, in this courtroom, the very  
4 same thing Jeff and his colleagues saw and heard: that OP-1  
5 provided a second chance, wonderful opportunities for a vastly  
6 improved life. Get these people back to their near-normal  
7 daily function. No more pain. I can sleep. I can walk. I  
8 can lift. And in some cases with trauma patients, I don't have  
9 to lose a limb. I don't have to lose a limb.

10 These are wonderful opportunities for surgeons. These  
11 are folks -- the gentleman here an example among them --  
12 they're wired to move. They're active people. They want to  
13 help. They want to achieve things. They want to accomplish.  
14 They want to use everything that's available to them to  
15 maximize their ability to get a good result for their patients.

16 So why's this important to go into this with you here?  
17 Well, in addition to the wonderful results themselves, far from  
18 any criminal intent of any kind, these results add to Jeff's  
19 store of understanding, knowledge and appreciation of the  
20 wonders that OP-1 brings to patients. Jeff and his colleagues  
21 are personally and professionally motivated by these success  
22 stories. They give them pride in what they do, in their work,  
23 and why they can offer surgeons a way out.

24 Now, surgeons. Very briefly. You're going to see and  
25 hear from several of them. These are the folks who deal with



1 the spine. Orthopedic surgeons and neurosurgeons, they both  
2 cover the human spine. Needless to say, they're highly  
3 educated, skilled and trained. I would consider them the  
4 fighter pilots of the surgical community, the very best of the  
5 best. They're busy people. You'll hear about their  
6 time -- their tight time clock and time management day in and  
7 day out. They have special surgery days. They do rounds.  
8 They have time set aside for new patients. They're not very  
9 casual in their workplace, as you might imagine. And they  
10 can't and don't tolerate folks on their team who don't show up,  
11 don't perform and don't come prepared for business and aren't  
12 prepared when the surgeon poses a question or asks for help.

13 Sales reps, the entire medical-device community, know  
14 this, including Jeff. This is a relatively small tight-knit  
15 surgical community, you'll learn from the witnesses on the  
16 witness stand. They stay up on the latest advancements and  
17 techniques in this kind of surgery. They talk to each other  
18 all the time. What better source than your colleagues, who are  
19 also your competitors for the surgical business? They go to  
20 the same lectures, they read the same literature, they attend  
21 the same conferences, and they're all on the internet. They  
22 want to be the best at what they do. And that's where it comes  
23 from, that information, all those sources.

24 Sales reps know this too. And you're going to -- in  
25 the operating room -- in the operating room -- this man's word

1 is law. He's got the first word, he's got the last word, and  
2 every word in between. That man. You're going to hear from  
3 some of them yourself. You'll see them on the witness stand.  
4 You can size them up all yourself. And you're going to see --  
5 what you're going to see and hear is that they call the shots.  
6 All of them. The who, what, when, where, how. All of it. And  
7 why? Ultimately, because they're accountable. They're  
8 responsible for that patient and the patient's family. They're  
9 the ones who walk out of the operating room and talk to the  
10 family. They're accountable at the end of the day.

11 So for that reason, among others -- and as I pointed  
12 out in the beginning of my comments but it bears repeating  
13 here -- you're going to learn that a surgeon is free to  
14 practice medicine without interference from the FDA. He's  
15 accountable. He's free to practice medicine. Surgeons will  
16 tell you that while there's a lot of science involved, once  
17 that surgical procedure begins, the incision is made, that's  
18 when the surgeon sees the landscape, actually sees what he's  
19 dealing with in that spine. And he sees where he's got room to  
20 act, what it is that he needs to do now that he couldn't see  
21 before.

22 And he'll tell you there's far more art than science  
23 involved in this. Now I've got a decision to make. How do I  
24 help this patient right here, right now? Each patient is  
25 different. No surprise there. Each procedure is

1 correspondingly different.

2           So you're going to hear a lot about things such as the  
3 space to be filled in the gutters. You'll hear about gutters,  
4 the space to be filled. The volume that I need -- the  
5 consistency. The handling -- the surgeon needs to deal with  
6 this now in the course of the procedure. The surgeon then  
7 believes in those. "I have to have everything available to me,  
8 all the tools and resources, everything. My training -- I  
9 bring to bear my training, my education, my experience, my  
10 expertise, and my independent exercise of medical judgment."

11           Now, the surgeon, as with any doctor, is completely  
12 free to make his or her own decisions, to elect, to prescribe  
13 or use for any purpose any drug or device lawfully on the  
14 market. He can reach anything that's lawfully on the market in  
15 the exercise of his independent medical judgment. That  
16 includes devices such as OP-1, Calstrux, or any other inert  
17 substrate, as we call it. That's the mixing material. And any  
18 combination of the two. Any combination of the two.  
19 Completely free to reach and use those things as he or she sees  
20 fit in the course of the surgical procedure.

21           Now, I expect that you'll see instances in this case,  
22 primarily emails, of Jeff's discussing with his colleagues  
23 various ways that spine surgeons in their discretion might --  
24 given the history of mixing and combining generally, how they  
25 might consider and ultimately decide, the doctors -- rather,

1 the surgeon calling the shots -- they might decide to combine  
2 these products. Their call. That's their shot.

3 And in doing so, you'll see that Jeff, as a  
4 knowledgeable device representative and regional sales manager,  
5 is genuinely trying to be helpful both to his sales reps and,  
6 in turn, to the surgeon in every case. That's all there is to  
7 this case, ladies and gentlemen. He's not hiding a thing.  
8 It's completely out in the open. He's acting completely in  
9 good faith rather than criminal, as the government charges  
10 here.

11 Now, you're going to learn that the medical-device  
12 community, including Jeff, all knew and understood these  
13 critical points: One, again, that the FDA may not interfere  
14 with a physician's judgment in the practice of medicine; and,  
15 two, that that judgment encompasses everything about the care  
16 and treatment of the patient including the use of medical  
17 devices, again, such as OP-1 and bone void fillers such as  
18 Calstrux, and that surgeon's judgment includes such decisions  
19 as to whether to use any device on-label or off-label.

20 Now, you heard a great deal from counsel yesterday  
21 about those terms, on-label, off-label. There's nothing bad  
22 about off-label. There's nothing bad at all. You'll hear that  
23 too from the physician. Oftentimes off-label is the standard  
24 of care. It's way ahead of the FDA. And I told you I wouldn't  
25 plow old ground, and I'm going to do my best to keep that

1 promise and move this along. But please bear this in mind when  
2 you listen to the evidence -- please bear these three points in  
3 mind: One, the FDA rules and regulations, the administrative  
4 rules and regulations, can be and often are complex, vague and  
5 inconsistently conveyed and interpreted. And that's when  
6 they're conveyed at all, which will be an issue in this case.  
7 I'm not going to get into the details of that last point, when  
8 they're conveyed at all, but pay particular attention -- I  
9 would ask you to pay particular attention to the evidence  
10 showing the disconnect between what John Houghton, the  
11 government's first witness, believes he achieved during his  
12 conference call with the sales force -- you're going to hear  
13 about that very shortly -- and what the members of the sales  
14 force actually took away from that call. You'll find two very  
15 different things, ladies and gentlemen. That's one: the FDA  
16 rules and regs. Complex, vague and inconsistently conveyed.

17 Two: Jeff genuinely believed and had every good-faith  
18 reason to believe that he and his reps not only could but  
19 should be prepared to respond to a surgeon's question or  
20 request for help and to, in fact, respond to that question or  
21 request. And that includes -- that encompasses any surgeon's  
22 question regarding mixing or combining two or more devices, if  
23 you will, such as OP-1 and Calstrux. He had every good-faith  
24 reason to believe that he could respond to a surgeon's request  
25 when it came to that, combining products, because the doctor is

1 completely free to do that.

2 Third and last: This is not a regulatory case. This  
3 has nothing -- this is not a diminished regulatory case. There  
4 are no administrative or regulatory charges against Jeff or any  
5 of these men or the company in this case. The Court's going to  
6 give you the law at the end of this case, but for now, please  
7 bear in mind this is a criminal case. There is far more at  
8 stake here.

9 And for this reason, the question for you as jurors  
10 will not be whether Jeff, or any particular sales rep or  
11 defendant, actually stayed inside or stumbled or strayed  
12 outside the white lines of any agency regs or standards or  
13 policies regarding promotion or anything having to do with the  
14 interaction with surgeons. That's not this case. It's not  
15 about staying within the white lines or stumbling or straying  
16 outside the lines.

17 Even if Jeff or a sales rep might later be found or  
18 thought to have run afoul of those rules or regs, the actions  
19 at issue, and you're going to hear about them in this case,  
20 were completely motivated by a genuine good-faith impulse to be  
21 of help, to actually help. And that's the polar opposite of  
22 criminal.

23 Now, very briefly, Ms. Winkler made a few comments on  
24 this conspiracy -- this conspiracy to defraud the FDA and to  
25 defraud surgeons. And a couple of points very quickly. First,

1 to defraud the FDA. There's not going to be any evidence,  
2 ladies and gentlemen, of Jeff targeting, entering into any kind  
3 of unlawful agreement to target or otherwise conspiring to  
4 defraud the FDA. He had no dealings with the FDA. There's no  
5 evidence of any dealings with the FDA. You will not see it.  
6 He couldn't find the FDA with a map. So that's not an issue in  
7 this case, respectfully.

8 Defraud surgeons. Ms. Winkler made a couple of points  
9 yesterday about Jeff and defrauding surgeons. And it takes two  
10 forms. The first is some comment about how surgeons are handed  
11 a ball of Calstrux, and Jeff allegedly trained a rep to say  
12 something like, "This is what OP-1 is going to feel like."  
13 That's in the course of a ride-along, where he goes into the  
14 various territories and he rides along with the sales rep.

15 Well, you'll learn that, actually, that's true.  
16 Surgeons will tell you, yes, that's what it does feel like.  
17 That's what it does feel like when it's combined. Again,  
18 they're looking for handling characteristics, volume. You'll  
19 hear these words: consistency, malleability. Will it work  
20 when I'm in a surgical operating room? You'll recall that  
21 mixing is a given; it's a standard of care at the time all of  
22 this is happening. Even before OP-1 came on the market.

23 Now, a surgeon's interested in the BMP, the bone  
24 morphogenic protein. And here that's the active ingredient.  
25 In our case it's the OP-1. The surgeon's interested in the

1 bone-growth qualities and properties of OP-1. But every  
2 surgeon that you're going to hear from, I expect, both  
3 government and defense, is going to tell you the surgeon is  
4 seriously interested in, again, the opportunity for  
5 scaffolding, for volume, the handling characteristics, and that  
6 comes only in a combined form, not just the active ingredient  
7 alone. No surgeon, ladies and gentlemen, in this case -- the  
8 evidence in this case -- sees this ball and thinks it's all  
9 OP-1.

10 Now, second, Ms. Winkler read to you yesterday an  
11 email, a message by Jeff in response to a question from  
12 headquarters about what kind of questions can you expect,  
13 anticipate in connection with a proposed letter going out.  
14 "What do you think the sales rep's going to say, what do you  
15 think the surgeon's going to say when they see this letter?"  
16 And in response, as she read, pointed out, identified,  
17 highlighted, one part of that email said, "Some doctors are  
18 handed the product prior to implantation and think it's all  
19 OP-1." Think it's all OP-1. The government wants to suggest  
20 to you that this is evidence of Jeff's knowledge of a  
21 successfully orchestrated fraud. Great. We got the doctors to  
22 think it's all OP-1.

23 Nothing could be further from the truth. First,  
24 Jeff's a sales guy. He's actually being frank and candid with  
25 the people back at headquarters. You send this letter out,



1 here's my views. Here's the things you're going to hear from  
2 the reps and from the surgeons. That's one. Not terribly  
3 artful, but he's been asked his opinion on the potential  
4 downsides of this controversial letter and he gives his views.  
5 He's completely straightforward to the folks back at  
6 headquarters.

7 Now, Jeff, as all medical-device reps, knows that all  
8 surgeons mix, but they aren't focused on the particulars of the  
9 scaffolding material; that is, the inert part. There's several  
10 dozens of those in the market. And you're going to hear  
11 about -- you'll hear and learn the identities of those on the  
12 market. And, in fact, Ms. Winkler told you yesterday Calstrux  
13 is nothing but a bone void filler. It's like spackle. No  
14 argument here. You won't get any argument from the surgeons  
15 who used it either. They'll tell you as much in this  
16 courtroom. It's the same substance that's found in this baby  
17 food.

18 Jeff knows this and that's what he's saying in his  
19 email. He knows this, the doctors are focusing in on the  
20 active ingredient. He knows it because the sales reps and the  
21 surgeons game plan every surgery. They discuss and identify  
22 the products to be used. And when the patient is ready for  
23 implantation of the combined OP-1 and Calstrux, the combination  
24 is no surprise to anybody in the room. No surprise. It's been  
25 played out, planned well beforehand. So it's completely

1 understandable, reasonable, predictable to believe that  
2 surgeons all think of it and call for it by name. "I'm ready  
3 for the OP-1." "I'm ready for the OP-1." That's the main  
4 player here. That's not proof of any conspiracy.

5 So what other basis can I say in response to this,  
6 they think it's all OP-1? Well, even aside from on its face,  
7 it's a statement of observation; it's a remark about how  
8 doctors behave and view things, about the busy lives and the  
9 shorthand way that surgeons refer to the active ingredient  
10 here. It's not a statement of intent. We want the doctors to  
11 think it's all OP-1. He's not saying that at all. That's one.

12 Two: The internal contributions -- you'll see it in  
13 the email -- it's two-faced. It's completely contradictory.  
14 The government's theory here. We got a two-pronged conspiracy.  
15 The first is: We're going to defraud doctors by handing them  
16 something immediately before surgery and tell them it's all  
17 OP-1. That's the first group. The second is: We're going to  
18 defraud them by sending them mixing instructions where there  
19 are two things involved. So one is: You hand them one thing,  
20 they'll think it's just one product; the other part of the  
21 conspiracy is we're going to defraud them by showing them how  
22 to mix.

23 Well, that's a pretty tall order, ladies and  
24 gentlemen, for a conspiracy. It calls for some pretty tightly  
25 coordinated action between and among the coconspirators, it

1 seems to me. So you'd better have a color-coded wall chart,  
2 make sure that you get your surgeons in the right group. We'll  
3 have a red group. These are the surgeons with it's all OP-1.  
4 And then we'll have a blue group, make sure we see that these  
5 surgeons are all in the mixing instruction part of the fraud.  
6 We want to make sure we don't blow our cover by putting  
7 Dr. Jones, who is at all OP-1, in the part of the mixing  
8 instruction part of the fraud. We don't want to do that; it  
9 will blow our cover.

10 Even aside from those points, there's the fundamental  
11 reality of this. It's open. It's obvious. It's completely  
12 transparent. Understand what the government's claiming here.  
13 This gentleman's coming in here and he wants to defraud the  
14 surgeon in the course of this procedure. Well, look at all the  
15 witnesses. They're all on top of each other here, one; two,  
16 and I mentioned the pre-game plan. We've gone over this  
17 beforehand. There is nothing surprising happening here at all.  
18 It's all according to plan; and, three, the accompanying  
19 documentation would choke a horse.

20 Among them you've got the informed consent, you've got  
21 booking forms, you've got circulating nurse notes, you've got  
22 operative notes, you've got delivered goods receipts.  
23 Ms. Winkler talked about it yesterday, the little stickers you  
24 pull off of the boxes from the products you actually use?  
25 Well, you're going to learn they go on the invoices and they

1 get faxed back to the company. That shows what product was  
2 used in the course of the surgery. That's how the company gets  
3 paid. The company wants to get paid. The hospital wants to  
4 know and the doctor wants to know for records what was used in  
5 that room. That's a strange way to carry out a conspiracy, it  
6 seems to me, to have all that documentation showing in real  
7 time who's doing what, using what, in what fashion, completely  
8 transparently. You're going to learn that all that  
9 documentation -- all of it -- is standard in the surgical  
10 community, and that, ladies and gentlemen, is all widely known  
11 to the members of the medical-device community, including Jeff.

12 So bottom line, with all that in mind, the  
13 government's pitch is this: This sales rep is going to try to  
14 wind up and blow a curveball past this gentleman, try to pass  
15 off two products as one in this room. He's going to put his  
16 career, his future, his family's future, his livelihood,  
17 everything on the line. He's going to pull off a federal  
18 felony within one of the most orchestrated, tightly controlled  
19 environments, second only maybe to Houston Control, in the  
20 world. And he thinks he could get past these highly skilled  
21 medical professionals with all that documentation, and he  
22 thinks he can get away with it time and again.

23 For this theory to fly, the government has to be  
24 suggesting -- and it has to prove to you, respectfully, ladies  
25 and gentlemen -- that the circulating nurse, the scrub nurse,

1 the surgical assistant, the radiology tech, everybody is in on  
2 this. Everybody is in on this except the surgeon, the  
3 so-called victim of the fraud. It doesn't fly at all. None of  
4 it.

5 Sales reps: You're going to be hearing from some  
6 sales reps. Basically, ladies and gentlemen, these are good  
7 folks, specialized education and training, all excited, proud  
8 to be working for a company known as an industry leader, and  
9 working together with other medical-device professionals,  
10 including folks back at headquarters known to have legal,  
11 regulatory, compliance training qualifications and  
12 responsibilities. They all take their job seriously. They all  
13 know the serious purpose of their business. They take great  
14 care to know about their benefits and believe in their products  
15 and the wonderful benefits that those products provide.

16 They stay current with the bone morphogenic protein  
17 literature and developments in the field. You see them, you'll  
18 see them here, routinely working alongside surgeons and their  
19 surgical teams. They're trusted by and responsive to the  
20 surgeons who are expert in their field, whom the surgeon  
21 expects and, indeed, requires to be present in the operating  
22 room, to be responsive to the surgeon's real-time needs.  
23 That's when we get in there, we make that incision. Now we see  
24 what we're dealing with. That surgeon's need for input and  
25 knowledge of the product.

1           So one last time, back to the brass tacks of the  
2 government's charges. They charge fraud. That's a broad term.  
3 And they use terms such as craft, trickery and deceit,  
4 dishonest means. But in plain English, it's lying, it's  
5 cheating and stealing. Lying, cheating and stealing. The  
6 charges say that Jeff, these men, company, are frauds,  
7 hucksters, charlatans. And here's the MO, basically. Spent  
8 all that time, effort and energy developing this wonderful  
9 product, and from the sales reps' -- regional managers'  
10 perspective, learn all about of those products, how they work,  
11 how the surgeon can use them to benefit a spine surgery  
12 patient, but don't do that for the benefit of anyone else. Do  
13 it to get yourself in the surgeon's office.

14           You fly under false colors. They think you're there  
15 to help them, but you're not. You're really there to make a  
16 quick buck. Do you remember Ms. Winkler's comments about it  
17 was all about to put money in their pockets? All of this to  
18 put money in their pockets. Gain their trust, gain their  
19 confidence, get into the operating room, work the con, lie to  
20 them, deceive them, pick their pockets and hustle out the door.  
21 That's the government's case.

22           From what you're about to see and hear in this  
23 courtroom, you will conclude that nothing about those charges  
24 square with what you see in this photo or who this man is.  
25 Nothing. Not for a minute. Rather, you're going to find

1 good-faith motivation at every turn, and that is good faith  
2 is a belief -- and I believe the Court will instruct you at the  
3 end of the case. Take your instruction from him. That is a  
4 belief or opinion honestly held even if it's later shown to be  
5 wrong. That's completely inconsistent with the specific intent  
6 to defraud, which the government must prove beyond a reasonable  
7 doubt.

8 Now, in conclusion, a surgeon has a relationship with  
9 the patient. A surgeon has a relationship with the patient,  
10 the sales rep has a relationship with the surgeon. Jeff wished  
11 to be responsive to the surgeon. He knows what the  
12 surgeon -- he understands. He's been familiar. He's been in  
13 these operating rooms. He's worked with surgeons before. He  
14 wants to be responsive to the surgeon and generally wished to  
15 be helpful in that surgeon's efforts to find a solution to the  
16 patient's condition and, most often, misery. And that, ladies  
17 and gentlemen, is how you carve out a long-term career in the  
18 medical-device field. And you make a good living at it, to  
19 boot. Nothing wrong with making a good living.

20 Now, the Court's going to tell you that no defendant,  
21 none, has any burden here. I don't have an obligation to make  
22 this opening statement. I don't have to question a witness,  
23 offer any evidence, cross-examine anybody, lift a finger.  
24 Nothing. The government has every burden all the time in this  
25 case to prove its case to you beyond a reasonable doubt. And

1 that includes the obligation of proving absence of good faith.  
2 I don't have to demonstrate to you good faith; they have to  
3 prove absence of good faith beyond a reasonable doubt.

4 So at the close of all the evidence, ladies and  
5 gentlemen, I will have an opportunity to come back before you a  
6 final time and speak with you and lay out for you the many ways  
7 that I believe the government has failed in its task to prove  
8 any charge against Jeff beyond a reasonable doubt. Rather, you  
9 will find that he acted in genuine good faith throughout here.  
10 And that's when I'll ask you formally that you clear Jeff's  
11 good name and return your verdict of not guilty.

12 Thank you for your attention.

13 \* \* \*

14 C E R T I F I C A T E

15  
16 I, Marcia G. Patrisso, RMR, CRR, Official Reporter of  
17 the United States District Court, do hereby certify that the  
18 foregoing transcript constitutes, to the best of my skills and  
19 abilities, a true and accurate transcription of my stenotype  
20 notes taken in the matter of Criminal Action No. 09-10330-GAO,  
21 United States v. Stryker Biotech, et al.

22  
23 /s/ Marcia G. Patrisso  
24 MARCIA G. PATRISSE, RMR, CRR  
25 Official Court Reporter

Date: January 13, 2012